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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,696	03/04/2002	Dov Borovsky	UF-214XCD1	5384

23557 7590 05/03/2004

SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
2421 N.W. 41ST STREET  
SUITE A-1  
GAINESVILLE, FL 326066669

EXAMINER
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JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/090,696	BOROVSKY, DOV	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 and 30-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/28/02, 10/27/03</u>   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED OFFICE ACTION

Applicant's election of Group V invention, claims 25-29, filed on 23 October 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Currently, claims 1-38 are pending, and claims 25-29 are under consideration. Claims 1-24 and 30-38 are withdrawn from further consideration as being drawn to a non-elected invention.

#### **Formal Matters:**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

#### **Objections and Rejections under 35 U.S.C. §101 and §112:**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 25-29 are directed to a method for identifying an insecticidal compound using a TMOF receptor by determining the binding said compound to the TMOF receptor. The specification discloses merely discloses *a portion of one* mosquito TMOF receptor, and there is no evidence in the specification that such a portion would even bind to TMOF or any ligand. Further, the prior art search does not reveal a TMOF receptor at the time of the present invention was made. Furthermore, the disclosed sequence of TMOF receptor suggests that the N-terminus of the receptor is missing, which, in many receptors, constitutes the ligand binding site of the receptor. Therefore, it is unclear whether the present sequence is a TMOF receptor, thus, no specific and substantial utility can be established for the polypeptide of SEQ ID NO:2 that is a

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partial sequence of a molecule based on the present disclosure. As such, the method of using the polypeptide does not have a specific and substantial utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make the claimed invention.

Furthermore, even if there were utility and enablement for the polypeptide of SEQ ID NO:2, enablement would not be commensurate in scope with claims 25-28, which are directed to a method for identifying a compound binding to any or all TMOF receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 25-28 are directed to a method for identifying a compound binding to a TMOF receptor, which, given the broadest interpretation, reads on a method for identifying a compound binding to any or all TMOF receptors. However, the specification merely discloses a portion of *one* TMOF receptor with sequence particularity, the mosquito TMOF receptor having SEQ ID NO:2. No other TMOF receptor of the same or different species meeting the limitations of these claims were ever identified or particularly described. Further, the specification provides no guidance or working example as to how to make a TMOF receptor other than that of SEQ ID NO:2. Therefore, it is in no way predictable what sequence structures of other TMOF receptors

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would be. As such, undue experimentation would be required of the skilled artisan to make a number of species of TMOF receptors that would be commensurate in its full scope of the claims.

Due to the large quantity of experimentation necessary to determine how to make a number of species commensurate in scope with the claims, the lack of direction/guidance presented in the specification regarding same, the absence of working example directed to same, the state of the art that has not established a family of TMOF receptors, and the breadth of the claims, which embraces a broad genus of TMOF receptors, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 25-28 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

The specification discloses *one* amino acid sequence with particularity, the mosquito TMOF receptor with SEQ ID NO:2. No other TMOF receptor meeting the limitations of these claims were ever identified or particularly described. Therefore, with the exception of the mosquito TMOF receptor of SEQ ID NO:2, the skilled artisan cannot envision the detailed chemical structure of the encompassed TMOF receptors of other species. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

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One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the mosquito TMOF receptor with SEQ ID NO:2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the method steps of the process. It is unclear what method/process applicant is intending to encompass in order to determine the binding of said compound to a TMOF receptor. The claim is further indefinite for failing to adequately and specifically identify the receptor protein used in the claim. In view of the prior art, the term "TMOF" has been applied to indicate different subject matters such as "trimethylorthoformate" (TMOF). It is, therefore, necessary that the applicant clearly defines the term "TMOF receptor" by sufficient identifying characteristics, such as SEQ ID NO: or specific functional properties, so as to clearly and distinctly indicate the protein that is the subject of the invention.

The remaining claims are rejected for depending from an indefinite claim.

**Prior Art:**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Borovsky et al. (FASEB journal, 1994, 8(3):350-5, provided by applicants) discloses a method of identifying a compound that binds to a TMOF receptor on mosquito gut membranes, and is capable of competing with the TMOF for the gut receptor.

**Conclusion:**

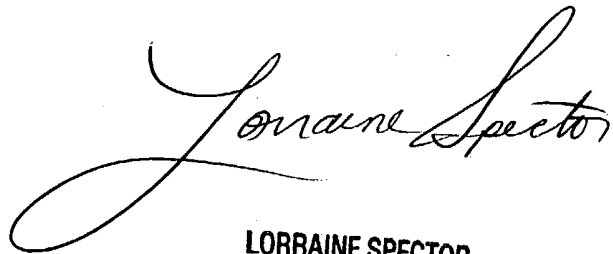
No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

LORRAINE SPECTOR  
PRIMARY EXAMINER

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
4/28/04